

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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AVENTIS PHARMA S.A., SANOFI-AVENTIS U.S., LLC	)	)
		)
		Plaintiffs, )
		) C.A. No. 07-721-GMS
		) (Consolidated)
v.	)	
	)	
	)	
HOSPIRA, INC., APOTEX INC., and APOTEX CORP	)	
	)	
	)	
Defendants.	)	
	)	

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**PLAINTIFFS' ANSWER TO APOTEX INC.'S AND APOTEX CORP.'s  
FOURTH AMENDED COUNTERCLAIM**

Plaintiffs/Counterclaim-Defendants Aventis Pharma S.A. and sanofi-aventis U.S., LLC (collectively, “sanofi-aventis”), for their answer to Defendants/Counterclaim-Plaintiffs Apotex Corp. and Apotex Inc.’s (collectively, “Apotex”) “Fourth Amended Counterclaims,” filed October 13, 2009, aver as follows:

**PARTIES, JURISDICTION, AND VENUE**

1. Upon information and belief, sanofi-aventis admits the allegations of paragraph 1.
2. Sanofi-aventis admits the allegations of paragraph 2, except denies that Aventis Pharma S.A. has a regular and established place of business in this district.
3. Sanofi-aventis denies the allegations of paragraph 3, except admits that Apotex purports to bring an “action . . . under the patent laws of the United States,” and that Apotex purports to base jurisdiction on 28 U.S.C. §§ 1331, 1338(a), 2201, and/or 2202.
4. Sanofi-aventis admits the allegations of paragraph 4.
5. Sanofi-aventis admits the allegations of paragraph 5.

## **BACKGROUND**

6. Sanofi-aventis admits the allegations of paragraph 6.
7. Sanofi-aventis admits the allegations of paragraph 7.
8. Sanofi-aventis admits the allegations of paragraph 8, except refers to 21 U.S.C. §§ 355(b) and (c)(2) for their contents.
9. Sanofi-aventis admits the allegations of paragraph 9.
10. Upon information and belief, sanofi-aventis admits the allegations of paragraph 10.
11. Upon information and belief, sanofi-aventis admits the allegations of paragraph 11.
12. Sanofi-aventis admits the allegations of paragraph 12, but adds that “Apotex’s untimely and de minimis production of a portion of its NDA complie[d] with neither its Offer of Confidential Access nor the requirements of 21 U.S.C. § 355(j).” (D.I. 1 ¶¶ 15-25.)
13. Sanofi-aventis admits the allegations of the first sentence of paragraph 13. The second sentence of paragraph 13 states a legal conclusion to which no response is required and is expressly denied insofar as the allegations pertain to the ‘582 patent in view of the fact that sanofi-aventis has given Apotex a covenant against suit on the ‘582 patent.
14. Sanofi-aventis admits the allegations of paragraph 14.

## **INEQUITABLE CONDUCT**

15. Paragraph 15 states a legal conclusion to which no response is required.
16. Paragraph 16 states a legal conclusion to which no response is required.

## **PROSECUTION OF U.S. PATENT NO. 5,698,582**

17. Sanofi-aventis generally denies the allegations of paragraph 17, and refers to the file history of the ‘582 patent for its contents.

18. Sanofi-aventis generally denies the allegations of paragraph 18, and refers to the file history of the '582 patent for its contents.

19. Sanofi-aventis generally denies the allegations of paragraph 19, and refers to the file history of the '582 patent for its contents.

20. Sanofi-aventis generally denies the allegations of paragraph 20, and refers to the file history of the '582 patent for its contents.

21. Sanofi-aventis generally denies the allegations of paragraph 21, and refers to the file history of the '582 patent for its contents.

22. Sanofi-aventis admits the allegations of paragraph 22.

**Failure To Disclose PR87 During Prosecution of the '582 Patent**

23. Sanofi-aventis denies the allegations of paragraph 23.

24. Sanofi-aventis denies the allegations of paragraph 24.

**Infectious Unenforceability**

25. Sanofi-aventis denies the allegations of paragraph 25.

**PROSECUTION OF U.S. PATENT NO. 5,714,512 ("THE '512 PATENT")**

26. Sanofi-aventis generally admits the allegations of paragraph 26, except refers to the file history of the '512 patent for its contents.

27. Sanofi-aventis generally admits the allegations of paragraph 27, except refers to the file history of the '512 patent for its contents.

**Failure To Disclose PR87 During Prosecution of the '512 Patent**

28. Sanofi-aventis denies the allegations of paragraph 28.

29. Sanofi-aventis denies the allegations of paragraph 29.

### **Failure to Disclose Etoposide/Teniposide**

30. Sanofi-aventis denies the allegations of paragraph 30, except admits that the depositions of the named inventors of the '512 and '561 patents were taken on April 21-25, 2009.

31. Sanofi-aventis denies the allegations of paragraph 31.

32. Sanofi-aventis denies the allegations of paragraph 32.

33. Sanofi-aventis denies the allegations of paragraph 33.

### **Insufficient Bases for Assertion of Avoiding Anaphylaxis**

34. Sanofi-aventis denies the allegations of paragraph 34, except admits that the '561 patent specification states that “[t]he anaphylactic shock phenomena which were observed with the solutions of the prior art are not observed with these solutions.” '561 Patent, col. 2, lines 48-51.

35. Sanofi-aventis denies the allegations of paragraph 35.

36. Sanofi-aventis denies the allegations of paragraph 36.

37. Sanofi-aventis denies the allegations of paragraph 37, except admits that the September 8, 1994 Amendment states that “[t]he anaphylactic shock phenomena which were observed with the solutions of the prior art are not observed with these solutions.”

38. Sanofi-aventis denies the allegations of paragraph 38, except admits that the July 30, 1997 Response states that “[t]he claimed composition is used to form an injectable solution that avoids the problems of anaphylactic shock or alcohol poisoning that may occur when either other solvents or an excess of alcohol is used.”

39. Sanofi-aventis denies the allegations of paragraph 39.

40. Sanofi-aventis denies the allegations of paragraph 40.

41. Sanofi-aventis denies the allegations of paragraph 41.
42. Sanofi-aventis denies the allegations of paragraph 42.
43. Sanofi-aventis denies the allegations of paragraph 43.

**Failure to Disclose JMC91 During Prosecution of the ‘512 Patent**

44. Sanofi-aventis denies the allegations of paragraph 44.
45. Sanofi-aventis denies the allegations of paragraph 45.

**PROSECUTION OF U.S. PATENT NO. 5,750,561 (“THE ‘561 PATENT”)**

46. Sanofi-aventis generally denies the allegations of paragraph 46, and refers to the file history of the ‘561 patent for its contents.

47. Sanofi-aventis generally denies the allegations of the first sentence of paragraph 47, and refers to the file history of the ‘561 patent for its contents. Sanofi-aventis denies the remaining allegations of paragraph 47.

48. Sanofi-aventis denies the allegations of paragraph 48.

49. Sanofi-aventis generally denies the allegations of paragraph 49, and refers to the file history of the ‘561 patent for its contents.

50. Sanofi-aventis denies the allegations of paragraph 50.
51. Sanofi-aventis denies the allegations of paragraph 51.
52. Sanofi-aventis denies the allegations of paragraph 52.

**Failure to Disclose Etoposide/Teniposide**

53. Sanofi-aventis denies the allegations of paragraph 53, except admits that the depositions of the named inventors of the ‘512 and ‘561 patents were taken on April 21-25, 2009.

54. Sanofi-aventis denies the allegations of paragraph 54.
55. Sanofi-aventis denies the allegations of paragraph 55.

56. Sanofi-aventis denies the allegations of paragraph 56.

**Insufficient Bases for Assertion of Avoiding Anaphylaxis**

57. Sanofi-aventis denies the allegations of paragraph 57, except admits that the '561 patent specification states that “[t]he anaphylactic shock phenomena which were observed with the solutions of the prior art are not observed with these solutions.” '561 Patent, col. 2, lines 48-51.

58. Sanofi-aventis denies the allegations of paragraph 58.

59. Sanofi-aventis denies the allegations of paragraph 59.

60. Sanofi-aventis denies the allegations of paragraph 60, except admits that the September 8, 1994 Amendment states that “[t]he anaphylactic shock phenomena which were observed with the solutions of the prior art are not observed with these solutions.”

61. Sanofi-aventis denies the allegations of paragraph 61, except admits that the July 30, 1997 Response states that “[t]he claimed composition is used to form an injectable solution that avoids the problems of anaphylactic shock or alcohol poisoning that may occur when either other solvents or an excess of alcohol is used.”

62. Sanofi-aventis denies the allegations of paragraph 62.

63. Sanofi-aventis denies the allegations of paragraph 63.

64. Sanofi-aventis denies the allegations of paragraph 64.

65. Sanofi-aventis denies the allegations of paragraph 65.

66. Sanofi-aventis denies the allegations of paragraph 66.

**Failure to Disclose JMC91 During Prosecution of the '561 Patent**

67. Sanofi-aventis denies the allegations of paragraph 67.

68. Sanofi-aventis denies the allegations of paragraph 68.

**COUNT I: Declaration of Non-Infringement,  
Unenforceability, and/or Invalidity of the '512 Patent**

69. Sanofi-aventis incorporates by reference its replies to paragraphs 1 through 68 as if fully set forth herein.

70. Sanofi-aventis denies the allegations of paragraph 70, except admits that Apotex purports to seek a declaration that no valid, enforceable claim of the '512 patent will be infringed by the manufacture, use, offer for sale, or sale of the Apotex products.

71. Sanofi-aventis admits the allegations of paragraph 71.

72. Sanofi-aventis denies the allegations of paragraph 72.

73. Paragraph 73 states a legal conclusion to which no response is required.

74. Sanofi-aventis denies the allegations of paragraph 74.

**COUNT II: Declaration of Non-Infringement,  
Unenforceability, and/or Invalidity of the '561 Patent**

75. Sanofi-aventis incorporates by reference its replies to paragraphs 1 through 74 as if fully set forth herein.

76. Sanofi-aventis denies the allegations of paragraph 76, except admits that Apotex purports to seek a declaration that no valid, enforceable claim of the '561 patent will be infringed by the manufacture, use, offer for sale, or sale of the Apotex products.

77. Sanofi-aventis admits the allegations of paragraph 77.

78. Sanofi-aventis denies the allegations of paragraph 78.

79. Paragraph 79 states a legal conclusion to which no response is required.

80. Sanofi-aventis denies the allegations of paragraph 80.

**COUNT III: Declaration of Non-Infringement,  
Unenforceability, and/or Invalidity of the '582 Patent**

81. Sanofi-aventis incorporates by reference its replies to paragraphs 1 through 80 as if fully set forth herein.

82. Sanofi-aventis denies the allegations of paragraph 82, and avers that this claim is not justiciable because sanofi-aventis has granted a covenant not to sue to Apotex on the '582 patent.

83. Sanofi-aventis admits the allegations of paragraph 83.

84. Sanofi-aventis denies the allegations of paragraph 84, and avers that this claim is not justiciable because sanofi-aventis has granted a covenant not to sue to Apotex on the '582 patent.

85. Sanofi-aventis denies the allegations of paragraph 85, and avers that this claim is not justiciable because sanofi-aventis has granted a covenant not to sue to Apotex on the '582 patent.

86. Paragraph 86 states a legal conclusion to which no response is required, and avers that this claim is not justiciable because sanofi-aventis has granted a covenant not to sue to Apotex on the '582 patent.

87. Sanofi-aventis denies the allegations of paragraph 87, avers that this claim is not justiciable because sanofi-aventis has granted a covenant not to sue to Apotex on the '582 patent.

88. Sanofi-aventis denies the allegations of paragraph 88, avers that this claim is not justiciable because sanofi-aventis has granted a covenant not to sue to Apotex on the '582 patent.

Sanofi-aventis states that the final paragraphs contain a prayer for relief to which no response is required. To the extent that a response is required, sanofi-aventis denies that Apotex is entitled to any relief.

Sanofi-aventis denies all allegations not expressly denied it otherwise responded to herein.

### **AFFIRMATIVE DEFENSES**

Sanofi-aventis asserts the following affirmative and other defenses. In asserting these defenses, sanofi-aventis does not assume the burden of proof with respect to any issue upon which applicable law places the burden of proof upon Apotex.

#### **First Affirmative Defense**

Apotex's counterclaims, in whole or in part, fail to state claims upon which relief can be granted.

#### **Second Affirmative Defense**

Apotex's counterclaims are not justiciable because sanofi-aventis has granted a covenant not to sue to Apotex on the '582 patent.

#### **Third Affirmative Defense**

Sanofi-aventis has not knowingly or intentionally waived any applicable affirmative defenses and reserves the right to assert and rely upon such other affirmative defenses as may become available or apparent during discovery proceedings. Sanofi-aventis further reserves the right to amend its Answer and/or its affirmative defense accordingly, and/or to delete affirmative defenses that sanofi-aventis determines during the course of subsequent discovery are not applicable.

ASHBY & GEDDES

*/s/ John G. Day*

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